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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,299

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James G. Barsoum

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10/16/2008

STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.
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EXAMINER

KELLY, ROBERT M

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,299	Applicant(s) BARSOU ET AL.	
	Examiner ROBERT M. KELLY	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,34,35,38,39,41,42,44,46,52 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,34,35,38,39,41,42,44,46,56 and 57 is/are allowed.
- 6) ☒ Claim(s) 52 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/15/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment and argument of 8/15/08 are entered.

Claims 1, 34, and 52 are amended.

Claim 58-66 are cancelled.

Claims 1, 34, 35, 38, 39, 41, 42, 44, 46, 52, and 55-57 are presently pending and considered.

Claim Status, Cancelled Claims

In light of Applicant's cancellation of claims 58-66, all objections and/or rejections of such claims are rendered moot, and thus are withdrawn.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendments, the rejections of Claims 1, 34, 35, 38, 39, 41, 42, 44, 46, 52, and 55-57 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for comprising new matter, are withdrawn.

To wit, the claims no longer require a generic promoter functional in hepatocytes.

Claim Rejections - 35 USC § 102, Wilson

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52 and 55 remain rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,001,557 to Wilson et al., for reasons of record.

The rejection is restated for clarity.

Wilson teaches production of adenoviruses by co-transfection of a shuttle vector containing the therapeutic minigene and missing essential genes, and a helper virus, carrying the genes required for production of virus, which may or may not be designed to be packaged efficiently (col. 5, paragraph 6). With regard to promoters active in the liver, the CMV promoter is taught, and such is functional in the liver (e.g., col. 8, paragraph 1). Moreover, by being in water, such claims encompass the pharmaceutically-acceptable carrier.

Further, the production of viral particles, when using the helper virus that is capable of being packaged, will necessarily produce the viral particles of helper virus and vector containing the therapeutic minigene.

Hence, the claims are anticipated.

Response to Argument, anticipation, Wilson

Applicant's argument of 5/16/08 has been fully considered but is not found persuasive.

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Applicant argues that the viral vectors of the claims are provided as viral particles, and reargues that Wilson does not teach viral particles when administered to the cell (pp. 8-9, paragraph bridging).

Such is not persuasive. Wilson teaches that "[p]referably, the helper virus is modified so that it does not package itself efficiently", which necessarily means that "less preferably", the virus does package itself efficiently, and hence, Wilson does teach compositions which are necessarily made by the method. Alternatively, because the preferable method is one that the helper virus is modified so that it does not package itself efficiently, such necessarily means that some inefficiently packaged adenovirus of the helper virus is packaged. With regard to the condition which is administered to the cell, such is irrelevant, unless it modifies the composition itself. The Examiner has been unable to identify the structural difference which would preclude the virus compositions made from being embraced by the composition claim which Applicant has proffered. I.e., intended use has no bearing unless it affects the structure of the composition.

Applicant argues through several citations that no composition of both adenoviruses are taught, unless they are conjugated (pp. 8-9).

Such is not persuasive. Wilson teaches making the compositions of adenovirus by the method which necessarily evolve compositions anticipating the claims, and specific references of examples do not preclude such. Further, it has been considered whether the compositions are taught, from the method of making, or whether they are obvious. However, the Examiner does not believe this requires an obviousness-type rejection, as the method of making as quoted in the citations above, and argument above, demonstrates that the compositions were contemplated as being obtained in the less preferable, as well as more preferable embodiments. It is simply a

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truism that the specific examples do not need to anticipate the claims, and the teachings themselves can anticipate, as is shown here.

Applicant argues that Wilson teaches shuttle vectors which are not adenovirus, and hence, it does not anticipate the claims (p. 9, paragraph 2).

Such is not persuasive. Rejections under anticipation are not limited to explicit examples, but can be obtained from the other teachings in a piece of Art.

Applicant argues the composition administered (p. 9, paragraph 3).

Such is not persuasive. The composition is what is rejected, and intended use has no bearing on the composition, unless it structurally changes the composition.

Conclusion

Claims 1, 34, 35, 38, 39, 41, 42, 44, 46, 56, and 57 are allowable.

Claims 52 and 55 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633